Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 27 February 2008 has been entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 27 February 2008 was filed after the mailing date of the Notice of Allowance on 29 November 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The closest art disclosure form the newly submitted information disclosure statement are the disclosures of U.S. Patent Publications 20060115869 and 20050239150, both by Bergman et al. and both of which have the same effective filing date of 15 April 2003 with a foreign priority date of April 2002. The instant claims are

drawn to a method of confirming a clinical diagnosis of a sepsis in a patient suspected of having sepsis the method comprising: a) determining the concentration of LIM and SH3 Domain Protein-1 (LASP-1) and at least one further biomarker for sepsis in a blood or serum sample from said patient; and b) comparing said concentrations to the corresponding concentration in a control sample, wherein an elevated concentration of a LASP-1 protein and at least one further biomarker for sepsis with reference to said control sample is indicative of sepsis, wherein said at least one further biomarker is procalcitonin, thus the instant application drawn to the confirmation of sepsis requires measurement of LASP-1 and procalcitonin. U.S. Patent Publication 20060115869 (which was allowed on 20 March 2008) is drawn to methods for the diagnosis of sepsis in a human patient comprising: (a) obtaining a blood, plasma, or serum sample from said patient; and (b) determining the presence and amount of human carbamoyl phosphate synthetase 1 or CPS 1 in said sample, wherein an elevated concentration of CPS 1 protein is indicative of sepsis, wherein step (b) alternatively comprises: performing a multi-parameter determination, wherein the presence and amount of CPS 1 is co-determined with at least one other sepsis marker and wherein the at least one other sepsis marker is chosen from procalcitonin, cancer antigen 19-9 (CA 19-9), cancer antigen 125 (CA 125), protein S 100B, protein S 100 A, soluble cytokeratin fragments, inflammin peptide, calcitonin-homologue peptide (CHP), LASP-1, peptide prohormone immunoreactivity, and C-reactive protein (CRP), thus the methods of the recently allowed U.S. Patent Publication 20060115869 requires measurement of CPS 1 and at least one other marker chosen from procalcitonin, cancer, CA 19-9, CA 125,

protein S 100B, protein S 100 A, soluble cytokeratin fragments, inflammin peptide, CHP, LASP-1, peptide prohormone immunoreactivity, and CRP. The methods do not recite the same method steps, namely, the claims of the instant application requires measurement of LASP-1 and one other marker that is calcitonin, and the U.S. Patent Publication 20060115869 requires measurement of CPS 1 and another marker chosen from the list in the immediately preceding sentence.

U.S. Patent Publication 20050239150 is drawn to methods for the early diagnosis and diagnosis, for the prognosis and the assessment of the severity and for the therapy-accompanying assessment of the course of sepsis and sepsis-like systemic infections and for the estimation of the risk of a sepsis risk patient through the formation of a sepsis, characterized in that the presence and/or amount of anti-asialo-GM1 antibodies (anti-AGM1 antibodies) and antibodies cross-reacting therewith in a biological fluid of a patient or sepsis risk patient are determined and conclusions are drawn from the presence and/or amount thereof with regard to the presence, the expected course, the severity or the success of a therapy of the inflammatory disease or sepsis or with regard to the risk of a sepsis risk patient, characterized in that at least one further parameter which is selected from the group consisting of the proteins procalcitonin, CA 125, CA 19-9, S100B, S100A proteins, LASP-1, soluble cytokeratin fragments, in particular CYFRA 21, TPS and/or soluble cytokeratin-1 fragments (sCY1 F), the peptides inflammin and CHP, peptide prohormones, glycine N- acyltransferase (GNAT), CPS 1 and CRP or fragments thereof is determined as part of the multiparameter determination. The methods do not recite the same method steps, namely, the instant

claims require measurement of LASP-1 and one other marker that is calcitonin, and the claims of the U.S. Patent Publication 20050239150 require measurement of anti-AGM1 antibodies and another marker recited in the immediately preceding sentence.

Finally, U.S. Patent Publication 20060234295, Bergman et al., which has an effective filing date of 5 December 2005, is drawn to methods for identifying proANP or partial peptides formed therefrom, which are not the C-terminal ANP (99-125; "ANP"), in biological fluids for medical diagnosis, prognosis and therapy-accompanying monitoring by means of a sandwich immunoassay using two antibodies which bind specifically to different partial sequences of N-terminal proANP (NT-proANP; proANP 1-98), characterized in that both antibodies bind to partial sequences in the midregional area of NT-proANP which extends from amino acid 50 to amino acid 90 of NT-proANP, characterized in that it is used for diagnosis, for determination of the severity and prognosis and for accompanying therapy control of sepsis, wherein it is carried out in a multiparameter assay in which at least one further parameter relevant to sepsis diagnosis is simultaneously determined, wherein the parameter, or the further parameters, relevant to sepsis diagnosis is or are selected from the group consisting of anti- ganglioside antibodies, the proteins procalcitonin, CA 125, CA 19-9, S 100B, S 100A proteins, LASP-1, soluble cytokeratin fragments, in particular CYFRA 21, TPS and/or soluble sCY 1F, the peptides inflammin and CHP, other peptide prohormones, glycine N- acyltransferase (GNAT), carbamoylphosphate synthetase 1 (CPS 1) and the C-reactive protein (CRP) or fragments thereof. The methods do not recite the same method steps, namely, the instant claims require measurement of LASP-1 and one

other marker that is calcitonin, and the claims of the U.S. Patent Publication and the claims of U.S. Patent Publication 20060234295 require measurement of NT-proANP and/or proANP 1-98 and one other marker recited in the immediately preceding sentence.

In summary, though the copending applications have some overlapping scope (measurement of LASP-1 is required in the instant claims and is an option in the claims of the copending applications), each of the applications focus on a different principal marker to be measured for the diagnosis and/or conformation of sepsis. Furthermore, the instant application does not teach the determination of CPS 1, anti-AGM1 antibodies or NT-proANP/proANP 1-98, which are required by the other three applications, respectively. Therefore the instant invention is patentably distinct and free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 8:00am - 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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